PUBLIC VERSION

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., *Plaintiff*, v. TEVA PHARMACEUTICALS USA, INC., ET AL., *Defendants.*	Civil Action No. 2:15-cv-1455-WCB LEAD CASE **FILED UNDER SEAL**

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY FOR LACK OF ENABLEMENT

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Each asserted claim recites an ophthalmic composition containing "acrylate/C10-30 alkyl acrylate cross-polymer" as an emulsifier. But "acrylate/C10-30 alkyl acrylate cross-polymer" is not a single substance; it is the description of a broad class of chemicals. In fact, *millions* of cross-polymers fall within this class—each with different compositions and properties. The common specification of the patents-in-suit lists one, and only one, emulsifier within this class of cross-polymers: Pemulen®.

Pemulen® is a trade name referring to an acrylate cross-polymer product. The specification does not describe the particular composition of Pemulen®, nor does it describe the properties of Pemulen®. More importantly, the specification provides no information that would allow a person of skill in the art to identify which of the millions of acrylate/C10-30 alkyl acrylate cross-polymers might work in the claimed ophthalmic composition other than Pemulen®. Most are not suitable for use in an ophthalmic emulsion; many are toxic. The specification provides no guidance to a person of skill in the art to figure out which members of the class work. Allergan's expert, Dr. Loftsson, admitted that it would very "difficult," and "very costly and time consuming" for one of skill in the art to determine if any particular cross-polymer in the class would work—never mind identify all cross-polymers that would work in the ophthalmic emulsion. As Dr. Loftsson admitted, "[i]t is too difficult and too complex to [determine if a given cross-polymer would work] and I don't think anyone will do it." Ex. A, Loftsson 258:12-14. Such a task represents the quintessential example of "undue experimentation."

It is possible, in some cases, that a single working example with no explanation or description might enable a skilled artisan to extrapolate her knowledge to the full scope of a claimed genus. But this is not one of those cases. The acrylate/C10-30 alkyl acrylate cross-

polymers are not a small, predictable class of chemicals. As Allergan's expert stated, "[y]ou don't know about the toxicology. You don't know the availability, the manufacturing" of different cross-polymers in the class. *Id.*, 258:20-21. For the patent-in-suit, the claim language is not commensurate in scope with what is enabled by the patent specification. Accordingly, the Court should find the asserted claims invalid as not enabled.

I. STATEMENT OF UNDISPUTED FACTS

The patents-in-suit issued from related applications having identical specifications. *See* Ex. B, U.S. Patent No. 8,629,111; Ex. C, U.S. Patent No. 8,633,162; Ex. D, U.S. Patent No. 8,642,556; Ex. E, U.S. Patent No. 8,648,048; Ex. F, U.S. Patent No. 8,685,930; and Ex. G, U.S. Patent No. 9,248,191. All asserted claims recite an "acrylate/C10-30 alkyl acrylate cross-polymer" as one of the excipients in the ophthalmic composition. Ex. B, claims 16, 17, 25, 26, and 27; Ex. C, claims 13, 14, and 24; Ex. D, claims 11, 18 and 19; Ex. E, claims 1, 11, 13, 14 15, and 23; Ex. F, claim 35; and Ex. G, claims 12, 13, 16, 22, 26, and 27.

Allergan's expert, Dr. Loftsson, conceded that "[acrylate/C10-30 alkyl acrylate cross-polymer] is a name of a *wide variety* of polymers." *Id.*, 245:16-17 (emphasis added). These polymers are formed by crosslinking an acrylate monomer (any salt, ester, or conjugate base of acrylic acid) with a C10-30 alkyl-substituted acrylate monomer. There are thousands of different acrylate monomers in the world, and many different ways that an acrylate can support a C10-30 alkyl substitution. There are therefore at least thousands—likely millions—of acrylate/C10-30 alkyl acrylate cross-polymers. *Id.*, 244:6-11, 261:1-5; Ex. H, Hanes Dep. Tr. at 109:23-110:2, 115:7-13, 120:4-7. Many cross-polymers in this genus have been synthesized and used in experiments. Some have never even been synthesized. Ex. A, 261:6-10. Many chemicals in this

class may be wholly unsuitable for ophthalmic use. *Id.*, 258:15-20. Some may be toxic. *Id.*, 258:20-21.

Loftsson confirmed that the phrase "acrylate/C10-30 alkyl acrylate cross-polymer" thus "describes a *group* of polymers . . . but only few of them are accepted for pharmaceutical applications." *Id.*, 244:24-245:8 (emphases added). As such, one of ordinary skill practicing the invention could not simply use *any* acrylate C10-30 alkyl acrylate cross-polymer as the emulsifier in the claimed composition:

> A. . . .[T]o say that you can choose from millions of polymers based on this [disclosure] is simply not correct. You are very, very limited by what you can use in pharmaceutical formulations, very, very much limited.
> . . .
> Q. . . . So you would say, [l]ook, you can't just take any acrylic cross-polymer that exists?
> A. No.

Id., 250:18-251:5. Loftsson went on to confirm:

> Q. If I came up with some [new] acrylate/C10-30 alkyl acrylate cross-polymer
> . . .
> it would take an enormous amount of testing, experimentation, costs in order to be able to use that in a topical ophthalmic solution; right?
> A. It will . . . yes, it would be very costly and time-consuming. You would say like this.
> Q. It would be very, very difficult; right?
> A. It is difficult, yes.

Id., 253:12-254:3.

None of the applications leading to the patents-in-suit describe, or even mention, how to make and use members the vast, variable class of cross-polymers represented by the term "acrylate/C10-30 alkyl acrylate cross-polymer." *See Id.*, 268:12-15 ("In your opinion, do the patents-in-suit teach a skilled artisan to make an acrylate C10 to 30 alkyl acrylate cross-polymer? A. No, I don't think so.") Instead, the patents merely disclose one single working example of an acrylate/C10-30 alkyl acrylate cross-polymer suitable for use in the claimed invention:

Pemulen® (the formulation described in Example 1, Composition II (0.05%)). *Id.* at 268:16-21 ("In your opinion what do the patents-in-suits teach a person of ordinary skill with respect to acrylate/C10 to 30 alkyl acrylate cross-polymers for use in preparing ophthalmic formulations? A. It actually tells you to use Pemulen . . .").

Pemulen® is a trade name for a product line containing various "polymeric emulsifiers," including one specific acrylate/C10-30 alkyl acrylate cross-polymer. Ex. H at 109:23-110:2, 115:7-13, 120:4-7. Carbomer Copolymer Type A, one of the acrylate/C10-30 alkyl acrylate cross-polymers sold as Pemulen®, is a particular species within the broad cross-polymer genus. Ex. A, 244:17-19. At the time of filing, Type A was the *only* cross-polymer that was known and used in ophthalmic solutions. Ex. A, 248:16-23.

Importantly, Loftsson did *not* opine that one of skill in the art reading the patent would understand the words "acrylate/C10-30 alkyl acrylate cross-polymer" in the context of ophthalmic therapy as a term of art meaning only Carbomer Copolymer Type A or Pemulen®. *Id.*, 254:4-18 (explaining that Loftsson did not redefine the term "acrylate/C10-30 alkyl acrylate cross-polymer" to mean only Pemulen®). Indeed, Loftsson twice confirmed that the asserted claims covered the entire class of acrylate/C10-30 alkyl acrylate cross-polymers:

> Q. . . .So I understand that that's not what formulators would[] want[] to do, but let's say that I . . . make myself a new cross-polymer, . . . and do everything that is found in the claims, but I'm going to use my new cross-polymer . . .
> . . .
> [W]ould I be within the scope of the claims or not?
> …
> A. I believe if you . . . prepare a hypothetical polymer emulsion within this class [the class being acrylate/C10-30 alkyl acrylate cross-polymers], then the patent would, yes, limit use of it[.]

Id., 259:1-19.

> Q. Now, let's say though that I . . . have my cross-polymer that I came up with on a piece of paper in a lab, . . . and I go through the testing . . . the huge amount of experimentation I have to do, and then I use it exactly in this formula in order to treat dry eye disease instead of Pemulen, that would be covered by the claims; right?
> …
> A. Hypothetically, yes.

Id., 263:23-264:10. Indeed, the scope of the claim term "acrylate/C10-30 alkyl acrylate cross-polymer" is not disputed, and its plain meaning is undisputedly broad enough to include every other acrylate/C10-30 alkyl acrylate cross-polymer beyond Type A/Pemulen®, whether or not such cross-polymers could feasibly be used in the claimed composition. *Id.*, 254:4-8.

Instead, Loftsson opined that a formulator would be *effectively* confined to using Type A as the emulsifier because the specification taught nothing else, and a formulator would not believe anything else was feasible:

> I don't know if the patents is [sic] teaching that to design and make new polymers within this class and I believe that a pharmaceutical formulator would never do that. It is too difficult and too complex to do it and I don't think anyone will do it.

Id., 258:9-14.

Loftsson nonetheless testified that he believed the asserted claims are not invalid for lack of enablement based on the specification's single working example using Pemulen®. *Id.*, 268:16-23. The basis for Loftsson's enablement opinion is his belief that a formulator, upon seeing the excipient "acrylate C10-30 alkyl acrylate cross-polymer," would choose the only acrylate C10-30 alkyl acrylate cross-polymer that was commercially available and routinely used in ophthalmic formulations—namely Pemulen®. *Id.*, 246:14-23. He goes on to state that no formulator would consider any other acrylate/C10-30 alkyl acrylate cross-polymer because doing so would require, among other measures, toxicological testing, "which costs huge amounts of

money." *Id.*, 250:11-17. Because he contends the use of Pemulen® is enabled, Loftsson concludes the claims are enabled. *Id.* But that is not the law.

The patentees initially limited the recited emulsifier to Pemulen® in all of the asserted claims. *See* Ex. I, U.S. Pat. App. No. 13/967,163 Claims filed 8/14/2013. The examiner rejected these original claims as being directed to a trade name. *See* Ex. J, U.S. Pat. App. No. 13/967,163 Office Action dated 10/17/2013, COE_JDG_PriorArt_0001811; Ex. A, 264:13-18. Rather than recite generic language describing the specific Pemulen® cross-polymer used in Example 1, however, the applicant amended the claims to recite the entire broad genus of acrylate/C10-30 alkyl acrylate cross-polymers to which Pemulen® belongs. *See* Ex. K, U.S. Pat. App. No. 13/967,163 Amendment filed 10/23/2013.

U.S. Patent No. 5,474,979 to Ding et al. ("Ding") also describes an ophthalmic cyclosporin composition that comprises Pemulen®. Ex. L, Ding 3:64-4:12. The claims in Ding recite "Pemulen." *See id.*, 6:6-41. Even so, the Ding specification described the specific composition of Pemulen® in generic language, *without implicating the entire genus of acrylate/C10-30 alkyl acrylate cross-polymers*:

> Pemulens are Acrylates/C10-30 Alkyl Acrylate Cross-Polymers. They are high molecular weight co-polymers of acrylic acid and a long chain alkyl methacrylate cross-linked with allyl ethers of pentaerythritol. They contain not less than 52.0 percent and not more than 62.0 percent of carboxylic acid groups. The viscosity of a neutralized 1.0 percent aqueous dispersion is between 9,500 and 26,500 centipoises.

Id., 4:4-12. *See also* Ex. A, 265:10-17 (admitting that it is possible to describe Pemulen® in generic language without capturing all acrylate/C10-30 alkyl acrylate cross-polymers); *id.*, 267:5-10 (admitting that a claim drawn to Pemulen® is narrower than a claim that recites acrylate/C10-30 alkyl acrylate cross-polymers). A claim that recites Pemulen® using generic language—such as the language used to describe Pemulen® in Ding—would therefore

undisputedly be narrower than a claim drawn to the genus acrylate/C10-30 alkyl acrylate cross-polymers in general. *Id.*, 267:5-10.

II. REASONS FOR GRANTING THE MOTION

There are simply no genuine disputes of material fact whether the full scope of the asserted claims are enabled; they are not. Summary judgment of invalidity is therefore appropriate as a matter of law. *See Rivera v. Houston Indep. Sch. Dist.*, 349 F.3d 244, 246 (5th Cir. 2003); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

A. The Single Working Example Disclosed Does Not Enable the Broad Genus Claimed Without Undue Experimentation.

The claim language recites a vast, unpredictable, and diverse class of cross-polymers, while the specification only discloses one member of the class (Pemulen®) in a single working example. *See* Ex. H at 109:23-110:2, 115:7-13, 120:4-7; Ex. A, 261:1-23. The scope of the claims is therefore not commensurate with the teachings of the specification, and the patents do not satisfy the quid pro quo requiring a patentee to enable the *full scope* of the claims. *See Alza v. Andrx*, 603 F.3d 935, 940 (Fed. Cir. 2010); *National Recovery Techs. Inc. v. Magnetic Separation Sys. Inc*., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999) ("The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.").

In re Wright is exemplary of claims drawn to a broad genus that were not enabled by disclosure of a single working example. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). There, the patentee sought to broadly claim "a live non-pathogenic vaccine for a pathogenic RNA virus," but the specification only disclosed a single vaccine that confers immunity in chickens against a particular avian RNA virus. *Id.* at 1559. The Federal Circuit noted that the claims broadly covered all vaccines for all RNA viruses, but RNA viruses are diverse and

complex. *Id.* at 1560. As such, a skilled artisan reading the specification would not have reasonably believed that success with one particular avian RNA virus could be extrapolated with a reasonable expectation of success to other RNA viruses; the disclosure was no more than an "invit[ation to] experimentation to determine whether other vaccines … could be constructed for other RNA viruses." *Id.* at 1562. The same is true here.

Acrylate/C10-30 alkyl acrylate cross-polymers possess diverse and complex properties and activity. Examples of essential, defining properties of cross-polymers include the method by and extent to which the acrylate monomer and alkyl acrylate are crosslinked and the percentages of each monomer in the overall composition. Each such cross-polymer is composed of two pieces: an acrylate monomer and a C10-30 alkyl acrylate. The acrylate monomer is hydrophilic, whereas the C10-30 alkyl acrylate monomer is hydrophobic. Changing their ratio or polymerization patterns (*i.e.*, how the two are bound) affects the material properties of any resulting cross-polymer. *Id.* As a result, each of the millions of cross-polymers that fall within the scope of the term "acrylate/C10-30 alkyl acrylate cross-polymer" would be expected to have different properties, including different therapeutic efficacies and toxicities. *See id.*

The patent specification here does nothing to reduce that uncertainty. It does not teach how to create the claimed cross-polymers. It does not describe or limit the essential properties of the cross-polymers used. It does not describe which types of the claimed cross-polymers show promise in an ophthalmic emulsion. In sum, there is no way for one of skill in the art to know what it is about Pemulen® that makes it successful in the example formulation, and how one might identify any other acrylate/C10-30 alkyl acrylate cross-polymers that would work similarly in an emulsion. *Cf. Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326 (Fed. Cir. 2005) (finding that one of skill in the art would have had to resort to undue

experimentation to make claimed formulations beyond those disclosed in the patent's two working examples). As such, a skilled artisan reading the specification would not have reasonably believed that success with one particular acrylate cross-polymer, a Pemulen, could be extrapolated with a reasonable expectation of success to other acrylate cross-polymers. At most, the specification is an "invit[ation to] experimentation to determine whether other" such cross-polymers might work. *Wright*, 999 F.2d at 1562.

In this regard, the asserted claims are also like those in *Wyeth v. Abbott Laboratories*, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (affirming summary judgment of lack of enablement where claims directed to a genus were not enabled by disclosure of a single species). In *Wyeth*, the claims covered a genus of rapamycin compounds, while the specification disclosed a single species, sirolimus. *Id.* Although the specification described some assays that one of skill in the art could use to determine whether a particular rapamycin would be structurally analogous and functionally equivalent to sirolimus, using those assays to test the full scope of thousands—potentially millions—of claimed rapamycin compounds constituted excessive experimentation. *Id.* The amount of experimentation required to practice the full scope of the claims was therefore undue, regardless of whether the nature of the experimentation (screening the structure and function of each compound) was routine. *Id.* at 1385-85.

Like the present case, the plaintiff's expert in *Wyeth* admitted that there were potentially millions of rapamycin compounds. *Compare id. with* Ex. A, 244:6-11 ("Q. There [are] a lot of acrylates out in the world; right? There [are] millions of them? ... A. Yes, you can form lots of different ac[rylates], yes."). The scope of the claims in both cases is therefore similarly broad, and the disclosure similarly limited to a single species. *See, e.g.*, *Id.*, 259:1-19. Unlike in *Wyeth*, however, the patents here do not disclose any assays or any other means by which one of skill in

the art could determine whether a particular acrylate cross-polymer is analogous and functionally equivalent to the single exemplified Pemulen® of the patents-in-suit. The disclosure here is therefore even more limited than the non-enabling disclosure in *Wyeth*. The single embodiment in the patent specification does not enable the full scope of the claims.

B. All of the *Wands* Factors Demonstrate That the Claims Are Not Enabled.

Applying the *In re Wands* factors also shows that the claims are not enabled. 858 F.2d 731, 737 (Fed. Cir. 1988). Determining whether experimentation required to practice the full scope of the claims is "undue" is a question of law, *see Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed. Cir. 1999), which traditionally turns on underlying factual considerations. *In re Wands*, 858 F.2d at 737. These factual considerations include (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *Id.*

Martek Biosciences Corp. v. Nutrinova Inc., illustrates how the *Wands* factors compel finding no enablement here. 520 F. Supp. 2d 537 (D. Del. 2007) *aff'd-in-part* (regarding lack of enablement of independent claims) 579 F.3d 1363, 1378 (Fed. Cir. 2009). Like Allergan's expert Dr. Loftsson, the expert in *Martek* testified that there were "a very large number" of species that fell within the claimed genus, and that it would take "an enormous amount of research" to find an unnamed species that would meet the limitations of the claim (addressing the first *Wands* factor). 520 F. Supp. 2d at 557.

As noted above, the breadth of the claims in this case is similarly vast. There are undisputedly millions of cross-polymers within the genus of acrylate/C10-30 alkyl acrylate

cross-polymers. The broader the claimed genus, the more likely the degree of required experimentation is undue. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004) ("The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be "unduly extensive.") (quoting *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996)).

The expert in *Martek* also explained that, as here, the specification did not teach how to "find, select out, and evaluate the range" of species claimed (addressing the second *Wands* factor). *Martek*, 520 F. Supp. 2d at 557. The nature of the present invention—ophthalmic pharmaceuticals—is complex and highly sensitive like the microorganisms claimed in *Martek*. Developing new excipients appropriate for use in human eyes is very difficult, and there is virtually no room for error concerning effectiveness or toxicity. Nothing in the specification teaches one of skill in the art to "find" or "select out" any acrylate cross-polymer other than Pemulen®, nor does it teach how to "evaluate the range" of such acrylate cross-polymers that might replace Pemulen® in the claimed composition. *Martek*, 520 F. Supp.2d at 557; Ex. A, 268:12-23 (explaining that the patents teach a person of ordinary skill to use Pemulen® only, and not how to select or use any other acrylate/C10-30 alkyl acrylate cross-polymer). Like the present case, the patent in *Martek* presented only one working example for a complex biotechnology invention that lacked predictability among its species and their properties (addressing the fourth and seventh *Wands* factors). *Martek*, 520 F. Supp. 2d at 557.

Martek's expert testified that the prior art did not teach that which the patent failed to disclose, and that "the skill in the art was not such as to eliminate the need for better teachings." *Id.* (addressing the fifth and sixth *Wands* factors). Similarly here, the prior art taught only one member of the genus; the same member disclosed in the lone working example. The skill in the

art here is not "such as to eliminate the need to better teachings," since, as Loftsson explained, it would be very difficult for a formulator to use any acrylate cross-polymer other than Pemulen® to practice the claimed composition. *Id.*; Ex. A, 268:12-23. The limited state of the prior art here also informs the analysis of the third *Wands* factor. The only known acrylate/C10-30 alkyl acrylate cross-polymer suitable for use in pharmaceutical compositions at the time of filing was type A (Pemulen®). *Id.*, 248:15-23. The state of the art, therefore, does nothing to help one of skill avoid any of the extensive experimentation that would otherwise be required to use an acrylate/C10-30 alkyl acrylate cross-polymer other than Pemulen® when formulating the claimed composition. *Id.*

Finally, the quantity of experimentation needed to make or use the invention based on the content of the disclosure is undisputedly "enormous." The extent and difficulty of the experimentation required to use any acrylate/C10-30 alkyl acrylate cross-polymer other than Pemulen® is so overwhelming, Loftsson contends that a formulator of ordinary skill in the art would not even consider it an option. The claims here therefore lack enablement for the same reasons that the claims in *Martek* lacked enablement.

The relevant considerations here are also indistinguishable from those supporting summary judgment of invalidity for lack of enablement in *Pharm. Res., Inc. v. Roxane Labs., Inc.*, No. 03–3357, 2006 WL 3231427 (D.N.J. Nov. 8, 2006); aff'd *Pharmaceutical Res., Inc. v. Roxane Labs., Inc.*, 253 Fed. Appx. 26, 31 (Fed. Cir. 2007) (unpublished). In that case, like here, the patent recited a broad genus of excipient (a surfactant) in a drug formulation. Just as here, the patentee argued that the claims were not as broad as suggested because a formulator practicing the claims would look to the smaller number of surfactants listed in the Pharmacopeia as recognized and approved for use in the relevant type of pharmaceutical, rather than the full

scope of surfactants recited. *See* 253 Fed. Appx. 29-30. Those claims, however, encompassed any choice of surfactant, thus capturing hundreds of potential surfactants within their scope. *Id.* The fact that a formulator would likely focus on a known and approved excipient is irrelevant to the scope of the claim language, and thus does not determine whether the claimed genus is overly broad. The law does not require that the specification enable only what a typical formulator might be interested in practicing. Rather, the law requires the specification to enable the *full scope* of the claims. *Id.* Allergan's reliance on conventional formulation strategies and established practices is no substitute for an enabling disclosure.

Allergan's expert testified that in the field of ophthalmic pharmaceuticals, it would be far too difficult for a formulator to use any excipient other than one that was specifically described in detail in the patent. Ex. A, 258:1-25. As a result, and given the breadth and nature of the claimed genus, one skilled in the art reading the specification of the patents-in-suit would have to engage in extensive and undue experimentation to use any acrylate/C10-30 alkyl acrylate cross-polymer other than the explicitly disclosed Pemulen®, even though the claims capture all acrylate/C10-30 alkyl acrylate cross-polymer. *Id.*, 263:3-264:10. That result does not satisfy the enablement requirement of 35 U.S.C §112(a).

C. Cases In Which A Single Embodiment Or Species Was Found to Enable a Larger Genus Do Not Apply Here.

Courts have sometimes held that the disclosure of a single representative species enables claims to a larger genus. *See* *Spectra-Physics, Inc. v. Coherent, Inc.* 827 F.2d 1524, 1533 (Fed. Cir. 1987); *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997) (explaining that claims to a genus require disclosure of a representative number of species, without any particular minimum number of representative species). Such cases are typically limited to *predictable* arts, such as mechanical technology, not unpredictable arts such

as chemistry. *Spectra-Physics*, 827 F.2d at 1533 ("If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment, and is not invalid for lack of enablement simply because it reads on another embodiment of the invention which is inadequately disclosed.")

Indeed, Dr. Loftsson did not disagree that using acrylate polymers in ophthalmic formulations is highly unpredictable. Ex. A, 258:1-25; *See Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (looking to the general level of predictability in the art, based on expert testimony about the difficulty of identifying new analogs within the claim scope). The level of disclosure required to satisfy the enablement requirement in pharmaceutical patents is often greater than in patents directed to other fields. *See Pharmaceutical Res., Inc. v. Roxane Labs., Inc.*, 253 Fed. Appx. 26, 31 (Fed. Cir. 2007) (unpublished). In pharmaceutical patents, the disclosure of a single species usually does *not* provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624 (CCPA 1938). In inventions involving physiological activity—considered particularly unpredictable—more than a single working example is often required. *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970).

While there have been exceptions to the general rule that a single species does not enable an entire genus in the unpredictable arts, this case does not fall within such an exception. The Federal Circuit decision in *Streck, Inc. v. Research & Diagnostic Systems, Inc.*, exemplifies such an exceptional case. 665 F.3d 1269, 1285 (Fed. Cir. 2012). In *Streck*, the claim scope encompassed two embodiments. *Id.* (identifying the two embodiments as true reticulocytes and reticulocyte analogs). The record established that skilled artisans would be able to practice both embodiments even though only one embodiment (reticulocyte analogs) was disclosed. *Id.* Here, the number of embodiments captured by the claimed class of emulsifiers is huge, and there is no

dispute that one of skill in the art would be unable to practice any embodiment other than a single Pemulen.

Additionally, disclosing a single *species* within a claimed genus (generally *not* enabling) must not be confused with disclosing a single *mode* of making and using an invention (generally enabling). *See, e.g.*, *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991) ("The enablement requirement is met if the description enables any mode of making and using the invention."). For instance, in *Johns Hopkins Univ. v. CellPro, Inc*., the Federal Circuit affirmed that the disclosure of a means for producing a small subset of claimed antibodies suffices to enable the claim to a larger genus of antibodies. 152 F.3d 1342, 1359-61 (Fed. Cir. 1998). In *Johns Hopkins*, however, the specification did not merely disclose one antibody species as purported support for claims to the larger genus. Rather, the patent disclosed many members of the genus, and method for *making* only one species. *Id.*

Here, the patent discloses *no* method for making any members of the claimed emulsifier genus. The specification discloses only the genus itself, and one example of a commercially available species. Cases like *Engel* and *Johns Hopkins*, addressing the requirement to disclose only one mode or method of practicing the claimed invention, thus address an entirely different question than the one at hand.

At bottom, the results of using acrylate cross-polymers in ophthalmic formulations are highly unpredictable, and acrylate cross-polymers are no exception. The lack of direction provided by the patentee here is particularly remarkable compared to the enormous scope of the claims. Not only does the specification gives just working example, but it never even disclosed the specific Pemulen® product used in that example, nor described any of Pemulen's components and properties. One skilled in the art could therefore not even determine what about

Pemulen® makes it effective in the claimed formulation, which could potentially reduce some of the experimentation required to discover other excipients comparable to Pemulen®. The totality of the undisputed record evidence thus confirms that undue experimentation is required to practice the full scope of the claims.

D. Allergan's Expert Testimony Does Not Establish a Material Dispute of Fact Regarding Enablement.

Allergan's expert testimony does not establish a material dispute of fact regarding enablement because Dr. Loftsson has conceded all of the relevant underlying factual considerations needed to support the legal conclusion of no enablement. Loftsson's conclusory statement that one skilled in the art could make and use "the formulations in the claims" without undue experimentation is flawed in several respects. *See* Ex. A, 269:11-17.

First, Loftsson's opinion applies the wrong legal standard. The law does not allow a patent claim to satisfy the enablement requirement by enabling only the preferred embodiment. Indeed, much of Loftsson's deposition testimony merely explains why using Type A/Pemulen® was the preferred embodiment, how one of skill in the art would not want to depart from that preferred embodiment, and why the preferred embodiment was enabled. *See, e.g., Id.*, 249:9-251:1. Whether anyone of ordinary skill in the art would *want* to depart from the preferred embodiment is not, however, relevant to whether the *full scope* of the claims are enabled. *See Enzo*, 188 F.3d at 1369 It is undisputed that the asserted claims, on their face, are far broader than the preferred embodiment. It is also undisputed here that one could not practice the claims beyond the preferred embodiment without an enormous amount of experimentation.

Second, Loftsson's opinion uses circular reasoning. He explains that a formulator would never consider departing from the preferred embodiment using Pemulen® as the acrylate C10-30 alkyl acrylate cross-polymer, because doing so would be difficult, prohibitively expensive, and

require extensive experimentation. In other words, no one would use any of the claimed acrylate C10-30 alkyl acrylate cross-polymers other than Pemulen® because the patents do not enable it. From that assessment, Dr. Loftsson asserts that a formulator would consider the recitation of "acrylate C10-30 alkyl acrylate cross-polymer" as effectively confined to Pemulen®. He then concludes that the claim is enabled, because he believes that the use of Pemulen® is enabled.

The law, of course, belies Dr. Loftsson's reasoning. Claim scope is not automatically limited to that which the patent enables. Rather, the claim language defines that which *must be* enabled. Dr. Loftsson agrees that the class of cross-polymers denoted "acrylate C10-30 alkyl acrylate cross-polymers"—and thus the scope of the claims—is far broader than Pemulen® alone.

Counsel for Allergan asked Dr. Loftsson on redirect whether a person of ordinary skill would "be able to make and use the formulations in the claims without undue experimentation." *Id.* 269:11-17. Dr. Loftsson answered "yes" (as he later admitted he was coached to do by his attorney during a deposition break). *See id.* 278:6-10. Despite of the impropriety of being asked for and giving a coached answer, that question and answer has no legal consequence. The question is *not* whether one of skill in the art could readily make and use *a* formulation in the specification—such as a formulation using a Pemulen®. Rather, the relevant question is whether one could make and use the *full scope* of the claims. On that question, the record is clear: one cannot. Moreover, an expert's conclusory statement that a claim is enabled (or not), without record evidence in support of that conclusion, does not create a genuine issue of material fact as to whether the claims are enabled. *See Pharmaceutical Res.*, 253 Fed. Appx. at 31 (citing *Automotive Tech. Int'l v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1282 (Fed. Cir. 2007)). Summary judgment that the claims are invalid for lack of enablement is therefore appropriate.

III. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant summary judgment and find that all asserted claims are invalid for lack of enablement.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing was served upon all counsel of record via e-mail on May 30, 2017.

/s/ *J.C. Rozendaal*
J.C. Rozendaal

CERTIFICATE OF AUTHORITY TO FILE UNDER SEAL

I certify that, pursuant to Local Rule CV-5(a)(7), the foregoing instrument designated as confidential in accordance with the previously signed Protective Order is authorized by the Court to be filed under seal.

/s/ *J.C. Rozendaal*
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